October 16, 2017

Dr. Jeff Morris
Acting Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington DC 20460

Re: Concerns about PMN Program

Dear Dr. Morris:

Thank you for meeting with several of us on September 18 to discuss EPA's premanufacture notification (PMN) program for new chemicals under section 5 of the Toxic Substances Control Act (TSCA). We felt the meeting was constructive and informative but came away with serious concerns about the "principles" for PMN review announced in EPA's August 7 press release. We are writing to underscore these concerns and to offer recommendations for greater transparency and public involvement in the PMN program.

The recently enacted Lautenberg Chemical Safety Act (LCSA) strengthens the PMN program and expands EPA's authority to restrict potentially unsafe new chemicals. We support these improvements and were pleased that EPA initially revamped the PMN review process to put in place the stronger protections required by Congress. However, the chemical industry has strongly opposed these enhanced protections and lobbied hard to reinstate the status quo before LCSA took effect. The August 7 press release provides worrisome evidence that EPA is backtracking from its strong approach to implementation in response to this industry pressure. Because of our strong legal and policy concerns about the directions announced in the press release, we request that you respond in writing to the issues discussed below.

Reducing the Backlog. Industry has taken EPA to task for creating a "backlog" of PMNs on which the Agency has not completed review. At our meeting, you indicated that EPA has reduced the backlog by temporarily transferring staff to the PMN program from elsewhere in the Agency. Since these additional resources likely will be unavailable in the future, EPA may be pressed by industry to achieve efficiencies by cutting corners on the rigor of PMN reviews. We would strongly oppose any approach that compromises the quality and thoroughness of the evaluation of individual PMNs in order to accelerate the review process. A truncated review process that gives short shrift to potential risks will only serve to save industry time and money at the expense of public health.

As you confirmed at the meeting, a major contributor to inefficiencies in the PMN program is industry itself, which has placed additional burdens on the EPA staff by filing PMNs that are incomplete or contain incorrect information and by failing to anticipate EPA concerns in their initial PMNs, necessitating supplemental submissions in response to staff information requests. These practices result in multiple cycles of review for individual PMNs and the expenditure of limited staff resources on extensive give-and-take with submitters. It is alarming that the August 7 press release seems to be condoning the practice of amended submissions when the Agency's goal should be to keep these submissions to a minimum by encouraging filing of robust and accurate PMNs at the start of the review process. While we were pleased that you supported this goal at our meeting, we request that you

describe the specific steps EPA will take to intensify its efforts to enhance the quality and responsiveness of industry submissions.

Shift to SNURs for Restricting Future Uses. The August 7 press release indicates that EPA no longer intends to issue section 5(e) orders "[w]here EPA has concerns with reasonably foreseeable uses, but not with the intended uses as described in a PMN or LVE application." Instead, the Agency plans to address these concerns solely through significant new use rules (SNURs) under section 5(a)(2).

We believe this change in approach is contrary to TSCA. EPA's safety determinations and regulatory actions under section 5 are expressly required to address risks presented by a new chemical under its "conditions of use." This term is defined under section 3(4) of TSCA to include the circumstances under which a chemical is "*reasonably foreseen* to be manufactured, processed, distributed in commerce, or disposed of" (emphasis added). If EPA identifies a reasonably foreseeable use raising concerns that meet the criteria for action under section 5(e), the law states that the Agency "shall" issue an order under that provision, whether the use is intended by the PMN submitter or not. EPA must then consider extending the order's protections to other manufacturers and processors under a SNUR, but the role of the SNUR is to supplement the order, not substitute for it.

The obvious benefit of a section 5(e) order in these circumstances is that it prevents the manufacture of the new chemical for the reasonably foreseeable use except under the restrictions EPA deems necessary to assure that the use is safe. In theory, a SNUR could also perform this function but it would need to be finalized by the end of the PMN review period so that the use does not fall through the cracks and the submitter and other firms are unable to commercialize it except under the SNUR restrictions.

We appreciate your desire to complete SNUR rulemakings on this expedited schedule, but the rulemaking process takes time and resources. For EPA to fast-track SNURs so they are promulgated within 90 days of PMN submission (or at most 180-days if the review period is extended) would be a daunting and probably impossible task. Indeed, our research has failed to disclose a single SNUR that EPA has finalized on substances subject to section 5(e) orders issued after LCSA took effect. The lack of SNURs several months after these orders were issued is contrary to the 90-day deadline for initiating rulemaking in section 5(f)(4) of TSCA[1] and calls into serious question EPA's ability to expedite SNURs on non-5(e) chemicals. For this reason, it would be not only unlawful but dangerous to public health and the environment for EPA to relinquish the leverage it has under section 5(e) to restrict future uses of concern before the start of production based on the uncertain prospect that, at some point in the future, they will be subject to SNURs.

We request that you explain why EPA believes it has authority to forego issuing section 5(e) orders on chemicals with reasonably foreseeable future uses that may present an unreasonable risk or otherwise meet the criteria for action under LCSA. We further request that you describe the steps you intend to take to assure that SNURs on these chemicals are finalized by the end of the PMN review period.

Requiring Evidence that Future Uses are "Probable." The August 7 press release indicates that future uses will be restricted if they are "not only possible but, over time under proper conditions, probable."

[1] Under section 5(f)(4), within 90 days of issuing an order under section 5(e), EPA must decide whether to promulgate a SNUR for a substance regulated under that order and either initiate the rulemaking process or explain why a SNUR is not needed. These deadlines do not apply to SNURs on non-5(e) chemicals and, as a result, EPA is under no obligation or schedule to issue such SNURs.

This sets an unjustifiably high bar for limiting future uses. To satisfy the "reasonably foreseen" standard in the law, there must be a plausible basis, supported by the characteristics of the new chemical and similar substances, to conclude that a chemical could reasonably be used for a particular purpose. A "probability" test, however, goes further, requiring EPA to demonstrate a likelihood that the use will occur. Such a showing would be difficult to make, given the many market uncertainties at the time a new chemical is initially commercialized, and in practice would discourage restrictions on reasonably foreseeable future uses.

Once EPA allows production of a new chemical to begin without a section 5(e) order or SNUR, it loses its ability to address risks to health and the environment except through the lengthy and resource-intensive risk evaluation and management process in section 6. Thus, it is in the public interest for EPA to maintain control over future uses of new chemicals to the full extent required under the law. If the new use does materialize, the restrictions in place under section 5(e) and the SNUR will provide assurance that it will be conducted safely. If the use never materializes, there would be no downside other than the upfront work of developing the section 5(e) order and SNUR.

Testing Based on Insufficient Data. The August 7 press release emphasizes that the purpose of testing under section 5(e) is "to reduce uncertainty in regard to risk" but then suggests that such testing is mainly to "address risk concerns that gave rise to a finding of 'may present an unreasonable risk'" under section 5(a)(3)(B)(ii). In fact, testing is also required whenever the available information is "insufficient to permit a reasoned evaluation of the health and environmental effects" of the new chemical under section 5(a)(3)(A). EPA's ability to require testing in the absence of adequate data, even if there is no direct evidence of risk, is a critical advance over the original TSCA and an important element of the strengthened PMN program. Further explanation of how EPA is using this authority is needed, including EPA's criteria for assessing the sufficiency of existing information, the number of orders it has issued to fill data gaps and the scope of the testing required.

Enhancing Transparency. The August 7 press release recognizes that "EPA needs to be more transparent in how it makes decisions on new chemicals" and commits the Agency to releasing and seeking public comment on documents that provide "more certainty and clarity" regarding the basis for new chemical determinations later this fall. We strongly support greater transparency. However, EPA should not focus simply on educating industry about the PMN process but should also seek to inform the public about EPA's efforts to protect health and the environment under section 5 and provide a basis for judging EPA's success in meeting the goals of the new law.

Right now, obtaining information on EPA's decisions on individual PMNs requires a complex, multi-step search of the Agency's Website and even with sustained effort, a meaningful picture of the Agency's actions is often unavailable. While section 5(g) requires EPA to publish a statement of its findings when it has concluded that a new chemical is not likely to present an unreasonable risk of injury under section 5(a)(3)(C), it is equally important for the general public and impacted communities to understand the nature and basis of EPA's actions to restrict chemicals because they present or may present an unreasonable risk, lack sufficient information for a reasoned evaluation of risk, or have the potential for substantial production and exposure or release. To provide this transparency, EPA should expeditiously post summary documents describing the rationale and supporting information for its safety determinations on such chemicals and the requirements it has imposed under sections 5(e) or (f).

Also critical for public oversight is an in-depth "trends analysis" for the PMN program as a whole. As we discussed at the meeting, this analysis should dig below the summary statistics that EPA now makes available and provide a more detailed breakdown of the number of PMNs falling into EPA's categories of concern, the types of uses identified in PMNs or by the Agency, the nature of testing requirements imposed, the amount and type of test data submitted, and the restrictions on exposure and release required. This analysis should be made available later this fall, when EPA provides additional information about its implementation of section 5 and seeks public comment.

We request that, in your response to this letter, you indicate whether EPA will undertake these steps to enhance the transparency of the PMN program.

CBI Substantiation. A top priority of the TSCA amendments was to reform the process for CBI protection by boosting transparency and imposing greater rigor and accountability on CBI claimants and EPA staff. Reflecting these goals, section 14(c)(3) requires substantiation of all CBI claims at the time of information submittal with the exception of a few narrow information categories. After a delay in interpreting this new requirement, on January 19, 2017, EPA announced that the substantiation provisions in amended section 14 were self-executing and should be implemented by all information submitters starting on March 20, 2017. It also required industry to substantiate CBI claims for earlier submissions by September 18, 2017 (recently extended by one month).

Although EPA's substantiation policies apply to the PMN program, we have been unable to determine whether PMNs submitted under the new law include CBI substantiation and whether the Agency is taking steps to assure compliance with its January 19 directives. We urge you to clarify this situation as soon as possible. We would be very troubled if PMNs – which are replete with CBI claims – are not adhering to the substantiation requirements.

In summary, we have several concerns about recent policy changes in the PMN program that we believe are unlawful or put protection of health and the environment at risk. We request that you provide a written response to this letter explaining how you plan to address these concerns and assure a strong and effective new chemical review process under LCSA.

We would be happy to answer questions or provide additional information. For this purpose, please con tact Bob Sussman, SCHF counsel, at bobsussman1@comcast.net.

Sincerely yours,

Liz Hitchcock, Government Affairs Director
Safer Chemicals Healthy Families

Patrick MacRoy, Deputy Director
Environmental Health Strategy Center

Eve Gartner, Staff Attorney
Earthjustice

Daniel Rosenberg, Senior Attorney
Natural Resources Defense Council

cc:
Maria Doa
Dr. Tala Henry
Chris Blunck
Greg Schweer
Nancy Beck